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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

LEHIGH VALLEY TECHNOLOGIES, INC., ENDO GLOBAL VENTURES, ENDO VENTURES LIMITED, AND GENERICS BIDCO I, LLC (d/b/a PAR PHARMACEUTICAL and QUALITEST PHARMACEUTICALS), Plaintiffs, v. SANDOZ, INC. AND UPSHER-SMITH LABORATORIES, INC., Defendants.	Case No. _____ **COMPLAINT AND DEMAND FOR JURY TRIAL** Document Filed Electronically

Lehigh Valley Technologies, Inc. ("Lehigh"), Endo Global Ventures ("Endo"), Endo Ventures Limited ("EVL"), and Generics Bidco I, LLC (d/b/a Par Pharmaceutical and Qualitest Pharmaceuticals) ("Par") (collectively, "Plaintiffs"), for their Complaint herein, allege as follows:

INTRODUCTION

1. Plaintiffs bring this lawsuit under section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)), the New Jersey Fair Trade Act (N.J.S.A. § 56:4), and the common law. Plaintiffs' claims against Sandoz, Inc. ("Sandoz") and Upsher-Smith Laboratories, Inc.

("Upsher-Smith") (collectively, "Defendants") arise from Defendants unfairly competing with Plaintiffs by virtue of their advertising, marketing, promoting, selling, and distributing of a Potassium Chloride for Oral Solution, USP, 20 mEq product, sold under the KLOR-CON brand, which is not approved by the U.S. Food and Drug Administration ("KLOR-CON Powder").

2. Pharma Research Software Solution, LLC ("Pharma Research") holds an approved New Drug Application ("NDA")—NDA No. 208019—for Potassium Chloride for Oral Solution, USP, 20 mEq ("Par's Potassium Chloride Powder"). Lehigh obtained an exclusive license from Pharma Research to manufacture, market, distribute, and sell Potassium Chloride Powder for Oral Solution, which is approved by the U.S. Food and Drug Administration ("FDA"). Endo is the exclusive licensee of Lehigh, and Endo appointed EVL distribution, supply, and commercialization rights. EVL, in turn, licensed rights to Generics Bidco I, LLC. Generics Bidco I, LLC does business as Qualitest Pharmaceuticals and distributes the Potassium Chloride Powder product under the Qualitest name. After Par Pharmaceutical, Inc.'s parent company was acquired by a subsidiary of Endo Health Solutions, Inc., Generic Bidco I, LLC also began doing business as Par Pharmaceutical.

3. The FDA granted approval of Par's product on August 19, 2015 for "the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient." (Exhibit 12 at 1.) Hypokalemia is a deficiency of potassium in the blood stream, and it is potentially life-threatening when not treated.

4. Par's Potassium Chloride Powder is the only FDA approved potassium chloride powder product in the United States. Other companies, including Defendants, sell versions of the drug that are not FDA approved without properly characterizing or representing the

unapproved status of the products in the marketing and sales of the products to the public. This causes confusion among consumers and results in Defendants obtaining an unfair advantage in the marketplace. This lawsuit arises from the sales and marketing of Defendants' product in competition with Par's Potassium Chloride Powder throughout the United States, including New Jersey.

5. Defendants intentionally mislead customers as to the FDA status and nature of KLOR-CON Powder, falsely suggesting and implying that it is FDA approved even though it is not. For example, Defendants falsely identify KLOR-CON Powder as a brand name drug. (Exhibit 4 at 40, 73.) This is literally false and misleading because Defendants' KLOR-CON Powder has no FDA approval and referring to a prescription product as a "brand" means that the product has been approved by the FDA pursuant to an NDA.

6. Defendants further mislead customers by commingling their unapproved KLOR-CON Powder with other KLOR-CON products that are FDA approved. Defendants sell a range of potassium chloride products under the brand name KLOR-CON in the United States pursuant to a 2014 exclusive license from Upsher-Smith. Under the agreement, Upsher-Smith manufactures the drugs and Sandoz has "exclusive US distribution rights for the branded potassium chloride line of products, KLOR-CON, and market[s] them under the Sandoz name…." (Exhibit 2 at 1; *see also* Exhibit 3 at 2.)

7. Several of the potassium chloride products sold by Sandoz under the brand name KLOR-CON have been approved by the FDA. These include FDA approved extended release tablets (NDA No. 019123) and extended release capsules (Abbreviated New Drug Application ("ANDA") No. 203106). The KLOR-CON potassium chloride powder that competes with Par's potassium chloride powder, however, *is not FDA approved*, but is nonetheless marketed under

the same KLOR-CON brand name as the approved products. In particular, it is marketed as KLOR-CON 20 mEq powder for oral solution.

8. Defendants further mislead consumers and pass off their KLOR-CON Powder product in the United States as an FDA approved drug product by, for example, making their unapproved product look like an FDA approved drug through the packaging and labeling, while simultaneously preying on the fact that pharmacists and consumers purchasing their products generally do not understand that drug companies like Defendants are selling unapproved drug products. (*See* Exhibit 6 at 1, 3.) Not only do Defendants design the packaging and labeling to look like an FDA approved drug, they also incorporate design elements from other FDA approved KLOR-CON products and fail to state that the KLOR-CON Powder product is not FDA approved.

9. Defendants also pass off their KLOR-CON Powder in the United States as a generic version of Par's FDA approved Potassium Chloride Powder product. On information and belief, Defendants provide obsolete, misleading, or false information to drug databases, such as Medi-Span, resulting in the database treating Par's approved Potassium Chloride Powder and Defendants' unapproved KLOR-CON as interchangeable. Such a linking misleads drug database users into believing that Defendants' unapproved Potassium Chloride Powder may be used interchangeably with Par's product even though Par's product is FDA approved and Defendants' product is not.

10. As a result of Defendants' false advertising, retail pharmacists are actually confused and deceived. For example, CVS states on its website that KLOR-CON 20 mEq Powder for solution is "FDA approved for the following conditions: Hypokalemia Prevention, Digoxin Toxicity, Hypokalemia." (Exhibit 5 at 2.)

11. Plaintiffs bring this action to enjoin Defendants' ongoing violations of the Lanham Act, the New Jersey Fair Trade Act, and the common law; and Plaintiffs seek to stop Defendants from unfairly competing with Par's Potassium Chloride Powder product by virtue of Defendants' false advertising, marketing, promoting, selling, and distributing of their unapproved KLOR-CON Powder product. Plaintiffs also seek damages resulting from Defendants' unfair and unlawful conduct as set forth in the Prayer for Relief.

THE PARTIES

12. Lehigh Valley Technologies, Inc. is a Pennsylvania corporation with a place of business in Allentown, Pennsylvania.

13. Endo Global Ventures is incorporated under the laws of Bermuda with a place of business at 22 Victoria Street, Hamilton HM 12, Bermuda.

14. Endo Ventures Limited is incorporated under the laws of Ireland with a place of business at Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

15. Generics Bidco I, LLC (d/b/a Par Pharmaceutical and Qualitest Pharmaceuticals) is incorporated under the laws of the state of Delaware with a place of business in Huntsville, Alabama.

16. On information and belief, Sandoz, Inc. is a Colorado corporation with its principal place of business and corporate headquarters at 100 College Road West, Princeton, New Jersey 08540.

17. On information and belief, Upsher-Smith is a corporation organized under the laws of the State of Minnesota, has a principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota 55369, and has a place of business at 840 Headquarters Plaza, North Tower–4th Floor, Morristown, New Jersey 07960.

JURISDICTION AND VENUE

18. This action arises under 15 U.S.C. § 1125(a), under the statutory law of the State of New Jersey, and the common law. This Court has subject matter jurisdiction for each of the claims herein:

(a) False or misleading representations of fact and unfair competition violate section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and this Court has original jurisdiction over such claims by virtue of 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338;

(b) Unfair competition and false advertising violate the New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq*., and this Court has supplemental jurisdiction over those claims by virtue of 28 U.S.C. § 1367(a); and

(c) Unfair competition violates New Jersey common law, and this Court has supplemental jurisdiction over those claims by virtue of 28 U.S.C. § 1367(a).

19. On information and belief, this Court has personal jurisdiction over Sandoz because its principal place of business is in New Jersey.

20. On information and belief, this Court has personal jurisdiction over Upsher-Smith because it has a place of business in New Jersey. Upsher-Smith is registered with the New Jersey Department of Health Food and Drug Safety Program under registration number 5003956 as a drug manufacturer and wholesaler. Upsher-Smith manufactures KLOR-CON Powder for sale in the United States. On information and belief, Upsher-Smith knows that KLOR-CON Powder is not FDA approved, but still puts it into the stream of commerce with knowledge that it would reach and confuse the public in New Jersey.

21. On information and belief, pharmacists and consumers purchasing Defendants' KLOR-CON Powder product located in the State of New Jersey have actually been misled by the

packaging and false advertising related to the unapproved KLOR-CON Powder. Sandoz has extensive contacts with New Jersey and this judicial district, and Sandoz has caused the KLOR-CON Powder product to be advertised, promoted, and sold in this judicial district. Upsher-Smith has also caused the unapproved KLOR-CON Powder product to be advertised, promoted, and sold in this judicial district, and Upsher-Smith knowingly allowed Sandoz to falsely advertise the product in New Jersey. The causes of action asserted in this Complaint arise out of Defendants' conduct in New Jersey, and elsewhere.

22. Both Sandoz and Upsher-Smith regularly conduct business in the State of New Jersey and throughout the United States. Sandoz markets and sells products to nationwide retail drugstore chains, including those with locations in this judicial district, as well as through nationwide wholesalers and distributors, and others who target this judicial district. Defendants have purposefully and voluntarily placed the unapproved KLOR-CON Powder into the stream of commerce with the knowing expectation that it will be purchased by consumers in this District, and with the result that it has in fact been purchased by consumers in this District.

23. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)–(c).

PAR'S FDA APPROVED POTASSIUM CHLORIDE POWDER

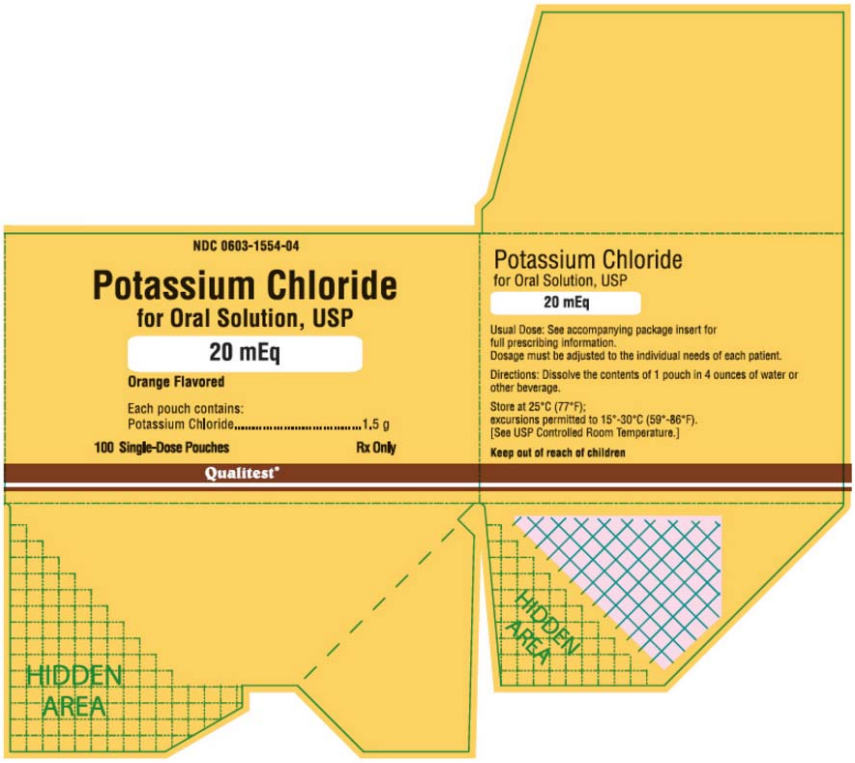
24. On October 24, 2014, Pharma Research submitted to the FDA an NDA (NDA No. 208019) for Potassium Chloride for Oral Solution, USP, 20 mEq, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2).

25. In seeking FDA approval of their Potassium Chloride Powder product, Plaintiffs undertook all the necessary steps and incurred the necessary expenses to establish the safety and efficacy of their Potassium Chloride Powder product for purposes of obtaining FDA approval. Plaintiffs gathered, analyzed, and reported relevant clinical data to the FDA and conducted an

extensive review of literature, and incurred regulatory, legal, development, and manufacturing costs. Plaintiffs invested a significant amount of time, resources, costs, and effort to establish the safety of their potassium chloride powder for oral solution product for treatment or prophylaxis of hypokalemia. To date, no other company has invested the time, resources, costs, and effort to successfully obtain FDA approval for a Potassium Chloride Powder product.

26. On August 19, 2015, Pharma Research obtained final FDA approval to market and sell the Potassium Chloride Powder product for "the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reductions is insufficient." (Exhibit 12 at 1.) Through a chain of agreements, Generics Bidco I, LLC subsequently obtained distribution rights to the NDA and markets its product under the names of Qualitest Pharmaceuticals and Par Pharmaceutical. Par's FDA approved Potassium Chloride Powder product—the only FDA approved Potassium Chloride Powder product—provides physicians and patients with a predictable, safe, and effective drug for the treatment or prophylaxis of hypokalemia, in adults and pediatric patients.

27. Par's product is packaged in 30 unit and 100 unit boxes. (Exhibit 1 at 6.) The FDA reviewed and approved the packaging for Par's Potassium Chloride Powder product, including the contents of the outward facing information for Par's approved Potassium Chloride Powder product, which is depicted below:



(Exhibit 1 at 8.)

28. The FDA's approval letter stated, any changes to the drug label (including carton and container labels) would "render the product misbranded and an unapproved new drug." (Exhibit 12 at 2.) In other words, as an approved—and therefore FDA regulated—product, no changes can be made to the label without preapproval from the FDA. (*See id.*)

29. Information regarding the FDA's approval of Par's Potassium Chloride Powder product is publicly available via the FDA website. The FDA maintains a list of all FDA approved drugs in an Approved Drug Products List with Therapeutic Equivalence Evaluations (commonly referred to as the "FDA's Orange Book"). As of June 22, 2016, Pharma Research, holds the only approved NDA of Potassium Chloride Powder for Oral Solution, USP, 20 mEq, and there are no approved ANDAs for Potassium Chloride Powder for Oral Solution USP, 20 mEq.

30. Plaintiffs have stockpiled the Potassium Chloride Powder product in order to meet

anticipated market demand for the product, in addition to dedicating the attendant quality control and manufacturing resources required for the production of inventory, all of which will require additional expenditures. Plaintiffs have the capability and capacity to meet the entire United States market's needs for Potassium Chloride Powder.

DEFENDANTS FALSELY ADVERTISE AND PROMOTE THEIR KLOR-CON POWDER AS AN FDA APPROVED DRUG TO MISLEAD CONSUMERS

31. On information and belief, after the August 19, 2015 date when Par's product received FDA approval, Defendants intentionally misled and continue to mislead customers as to the FDA status and nature of KLOR-CON Powder, falsely suggesting and implying that it is FDA approved even though it is not.

32. Defendants' KLOR-CON Powder is not FDA approved pursuant to an NDA, and it is not a generic version of an approved drug pursuant to an ANDA. 21 U.S.C. § 355(b), (j).

33. Defendants' KLOR-CON Powder is also not exempt from FDA approval under the original Federal Food & Drugs Act in June 1906 ("the 1906 Act"), the 1939 Federal Food, Drug, and Cosmetic Act ("the 1938 FDCA"), or the 1962 amendments to the 1938 FDCA. 21 U.S.C. § 1 (1906) (repealed in 1938 by 21 U.S.C. § 329(a)); 21 U.S.C. § 321(p)(1) (1938); Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781–82 (1962).

34. Whereas unapproved prescription drugs—like Defendants' KLOR-CON Powder—are not regulated by the FDA, approved drugs—like Par's Potassium Chloride Powder—are heavily regulated by the FDA. For approved drugs, the FDA preapproves drug and promotional labels and regulates advertisements. *See* 21 U.S.C. §§ 321(m), 352(n); 21 C.F.R. §§ 202.1(e)(1), (3), (l)(2), 201.100(d)(1)–(3).

35. The FDA approval status of a prescription drug is material to purchasers because

approved drugs provide purchasers assurance as to the quality of the product not afforded to unapproved prescription drugs. Because the marketing of unapproved drugs is not FDA regulated, such marketing may present a serious safety issue. (*See* Exhibit 11 at 1; *see also*, Exhibit 9 at 2; Exhibit 10 at 3.) For example, 40 infants died in the early 1980s from taking unapproved Vitamin E intravenous injections (E-Ferol). (Exhibit 10 at 11.) Defendants currently market and sell their unapproved Potassium Chloride Powder for use as a prescription drug to treat serious health conditions, and such marketing and selling is conducted outside the scrutiny of the FDA.

36. On information and belief, if pharmacists knew that Defendants' product was unapproved, they would not purchase it, and would not dispense it to patients. Despite pharmacists' preference for FDA approved prescription drugs, pharmacists are easily misled to purchase and dispense Defendants' product because they believe that all prescription drugs are FDA approved. For example, a nationwide survey of 500 pharmacists found that 91% thought all products they dispense are FDA approved. (Exhibit 6 at 3.) The FDA also recognizes that healthcare providers are confused by unapproved drugs:

> Many healthcare providers are unaware of the unapproved status of drugs and have continued to unknowingly prescribe them because the drugs' labels do not disclose that they lack FDA approval. In addition, since many unapproved drugs are marketed without brand names and have been available for many years, it is often assumed that these unapproved drugs are generic drugs. This is not correct. Generic drugs have been evaluated and approved by FDA to demonstrate bioequivalence to a brand name reference drug.

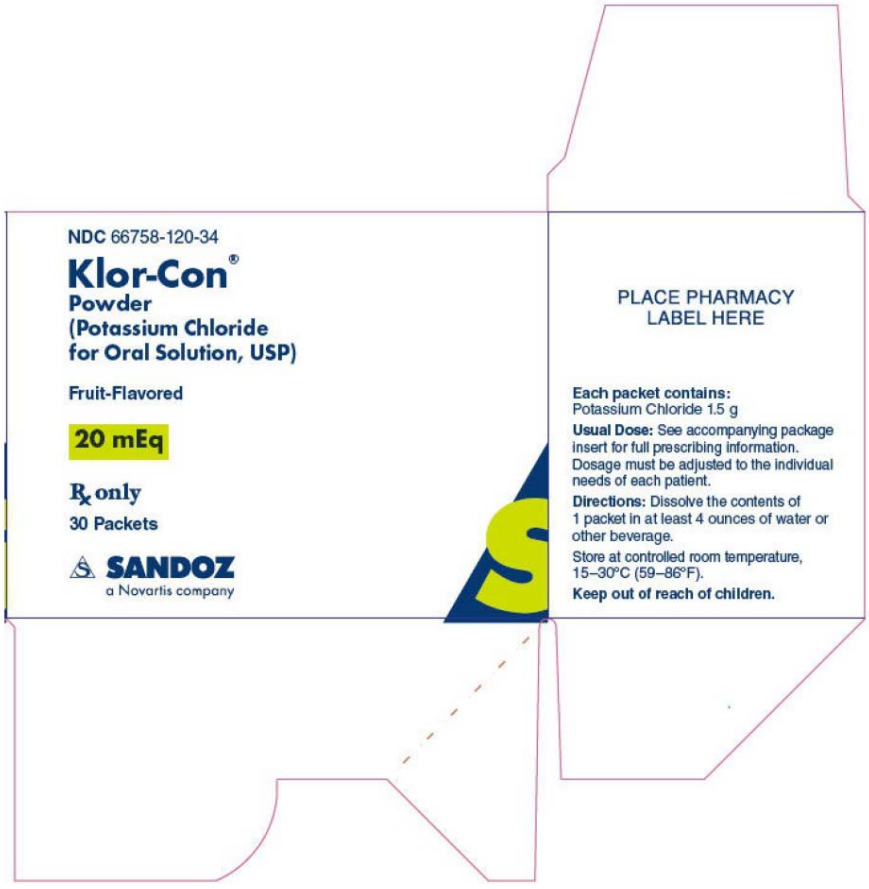
(Exhibit 7 at 1.)

37. Preying upon the misconception of pharmacists, healthcare providers, and the public, Defendants falsely advertise themselves as a generic drug company selling "generic" versions of FDA approved prescription drugs and falsely advertise their KLOR-CON Powder as

an approved drug. Because customers are misled to believe Defendants' product is FDA approved, customers choose to purchase Defendants' product over Par's product, thereby, directly harming Par.

Defendants' Product Packaging for KLOR-CON Powder Is Misleading Because It Omits the Material Fact That It Is Not FDA Approved

38. Defendants intentionally attempt to make their product packaging look like an FDA approved drug, and Defendants' product packaging hides the fact that it is an unapproved drug product, as depicted below:



(Exhibit 23 at 1.)

39. Customers of Defendants' KLOR-CON Powder cannot know whether the product is FDA approved or unapproved by looking at the packaging because Defendants omit any

disclaimer or notification on the product packaging indicating that the KLOR-CON Powder is unapproved by the FDA.

40. Defendants' product packaging for their KLOR-CON Powder product creates the false impression that it is an FDA approved drug because the box indicates that the drug is prescription only, *i.e.*, "Rx only."

41. Defendants further omit any disclaimer on their package insert to inform customers that the KLOR-CON Powder is not approved by the FDA. (Exhibit 13 at 1–2.) Instead, Defendants' package insert is designed to resemble a package insert approved by the FDA. For example, it incorporates similar sections and uses similar font and coloring.

42. Because Defendants' product, product label, advertising, and packaging are not FDA approved, their advertising is not pre-approved by the FDA. In contrast, Par's Potassium Chloride Powder product, product label, advertising, and packaging are regulated. This gives Defendants a competitive advantage over Par, especially because customers do not know that Defendants' product is not FDA approved. For example, because Defendants' product is not regulated by the FDA, Defendants may advertise indications and usage of their drug outside any approved indications and usage. Whereas Par's Potassium Chloride Powder product is only indicated "for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose restriction is insufficient," (Exhibit 12 at 1), Defendants' package insert states the following:

> **Indications and Usage**
> 1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis; in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.
> 2. For prevention of potassium depletion when the dietary intake of potassium is inadequate in the following conditions: patients receiving digitalis and diuretics for congestive heart failure; hepatic cirrhosis with ascites; states of aldosterone excess

> with normal renal function; potassium-losing nephropathy and certain diarrheal states.
> 3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

(Exhibit 13 at 1). Pharmacists and customers are misled to believe that Defendants' KLOR-CON Powder has more uses than Par's Potassium Chloride Powder, making it more desirable for pharmacists to stock at their pharmacy.

43. On information and belief, Defendants' omission of the material fact that their KLOR-CON Powder is not FDA approved from their packaging and package insert deceives, or has the capacity to deceive, a substantial segment of customers, including pharmacists.

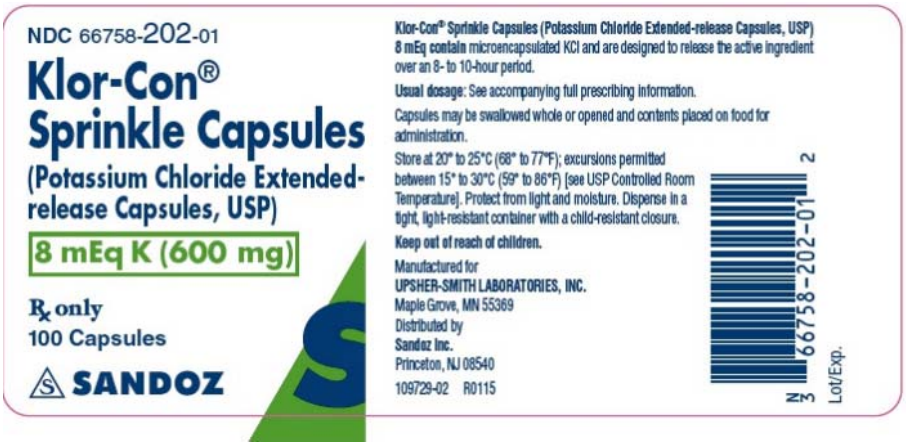
Defendants Bundle Their KLOR-CON Products under the Same Trademark to Mislead Consumers about the FDA Approval Status of Their KLOR-CON Powder

44. Defendants sell both approved and non-approved potassium chloride products under the common brand name KLOR-CON. In their advertising, Defendants make no distinction between their FDA approved KLOR-CON products and the unapproved KLOR-CON products, and refer to the bundle of products as their KLOR-CON product-line. For instance, when Sandoz announced its agreement with Upsher-Smith to obtain exclusive U.S. distribution rights, Sandoz stated:

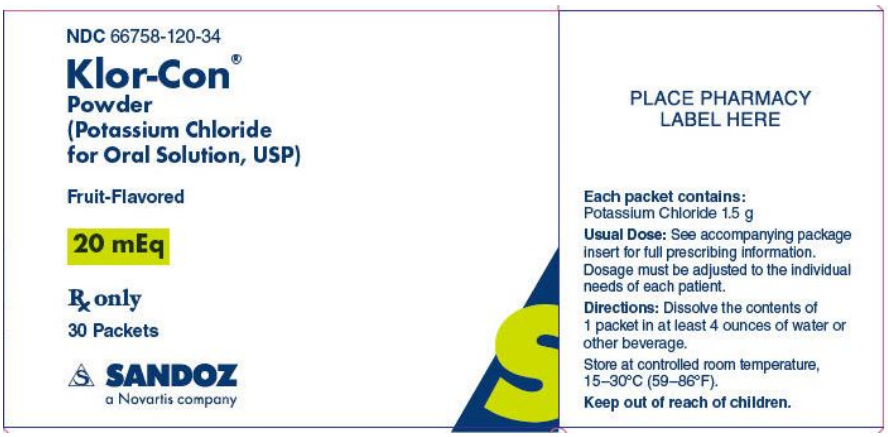
> Sandoz today announced an agreement with Upsher-Smith to obtain exclusive US distribution rights for its branded potassium chloride line of products, KLOR-CON®, and market them under the Sandoz name . . . . "This agreement expands and strengthens our current relationship with Upsher-Smith and helps us create a leading potassium chloride business[.]" . . . "With our extensive distribution system, we will be able to improve patient access to these products while increasing efficiencies and effectiveness."

(Exhibit 2 at 1.) In this press release statement, Sandoz draws no distinction between the FDA approved form of KLOR-CON and the unapproved KLOR-CON Powder. In fact, in the same press release, Sandoz described itself as "a global leader in the generic pharmaceutical sector." (*Id*. at 2.) Because "generic" drugs are FDA approved drugs pursuant to an ANDA, the press release as a whole misleads customers who read it into believing that all KLOR-CON products, including KLOR-CON Powder are FDA approved. Purchasers who learn that certain KLOR-CON products are FDA approved will be misled into falsely believing that all KLOR-CON branded products are FDA approved.

45. To further mislead customers, Defendants use similar packaging for both their FDA approved KLOR-CON extended release capsule and their unapproved KLOR-CON Powder. The FDA approved KLOR-CON extended release capsule packaging is depicted below:



(Exhibit 24.) The unapproved KLOR-CON Powder packaging is depicted below:



(Exhibit 23.) The similarity between the labels for the two products misleads customers.

46. Defendants also mislead customers through a full color catalogue called "The Pocket Guide: Generic to Brand Reference and Pharmacy Facts" ("the Pocket Guide") which Sandoz makes available on its website and distributes to existing and potential customers. In the Pocket Guide, Sandoz explains that the guide "has been designed as a quick reference for generic pharmaceuticals and their corresponding brand names." (Exhibit 4 at A-1.) The Pocket Guide makes no distinction between those drugs that are approved or unapproved by the FDA, and implies that they are all FDA approved by referring to each drug as either "brand" or "generic."

47. In the Pocket Guide, Sandoz lists "KLOR-CON® POWDER" as a "brand" name for the "generic" drug "Potassium chloride, powder for solution." (Exhibit 4 at 40, 73.) This is literally false and misleading because Sandoz's potassium chloride powder is not FDA approved, and calling it "generic" implies that it is FDA approved pursuant to an ANDA. Sandoz's website states: "Generic medicines have to be safe and effective to be approved by the FDA." (Exhibit 14 at 2.) In the Pocket Guide, Sandoz also refers to the "KLOR-CON® POWDER" as the brand version of generic potassium chloride powder, which is literally false and highly misleading because Sandoz's KLOR-CON Powder has no FDA approval whatsoever.

Sandoz Misleads Customers by Stating and Implying that All of Its Products Are Generic

48. Sandoz also misleads customers by publicly stating and implying that all its products are FDA approved. Sandoz markets itself as a leader in "generic" drugs, and affirmatively implies that all of Sandoz's products are generic and FDA approved. On its website, Sandoz states it is "is a world leader in generic pharmaceuticals" (Exhibit 15 at 1), and further states that "[its] core business lies in the development, production and distribution of high-quality, affordable generic medicines" (Exhibit 16 at 1). Sandoz also states, "Generic medicines have to be safe and effective to be approved by the FDA. The FDA also requires generic drug manufacturers to meet the same requirements for strength purity, and quality as the original manufacturer and follow the same strict 'Good Manufacturing Practices.'" (Exhibit 14 at 2.) Sandoz's public statements regarding its position as a market leader in generic drugs and that all generic drugs are FDA approved misleads customers into believing that all of Sandoz's products are FDA approved, including the KLOR-CON Powder product.

49. A customer attempting to determine whether the KLOR-CON Powder product is an authentic, FDA approved drug is misled by reviewing Sandoz's public statements about its business and products. Furthermore, even though Sandoz lists certain products on its website, Sandoz conspicuously does not mention the KLOR-CON Powder product, let alone state that it is unapproved; promoting further confusion about the nature of the KLOR-CON Powder product. Sandoz's product webpage omits any statement that Sandoz offers any prescription drugs that are not FDA approved.

50. On information and belief, because of the public statements that all of Sandoz's products comply with FDA guidelines and that its products constitute generic pharmaceuticals, customers of the unapproved KLOR-CON Powder product reasonably, albeit falsely, believe the

product to be FDA approved. On information and belief, Defendants do not want their customers to know before purchasing the KLOR-CON Powder product that it is not FDA approved. Upsher-Smith is complicit in Sandoz's advertising of Defendants' unapproved KLOR-CON Powder and knows or should know that Sandoz intentionally hides material facts from customers.

Defendants Mislead and Deceive Wholesale Distributors, GPOs, IDNs, Price Lists, Pharmacists, and Doctors as to the Unapproved FDA Status of the KLOR-CON Powder

51. Defendants mislead customers by not identifying their product as "unapproved" to wholesale distributors, who purchase the KLOR-CON Powder directly from Sandoz, and previously, from Upsher-Smith. Wholesale distributors include AmeriSourceBergen Corporation, Cardinal Health, Inc., H.D. Smith Wholesale Drug Company, McKesson Corporation, and Morris & Dickson Company. On information and belief, such companies purchase Defendants' KLOR-CON Powder without knowledge that Defendants' product is not FDA approved, and turn around and sell it to pharmacies that are also unaware that the product is "unapproved."

52. Because Defendants do nothing to identify the product as "unapproved" on their product packaging or on their websites, wholesale distributors cannot accurately describe Defendants' KLOR-CON Powder as not FDA approved. As a result of Defendants' misconduct, the databases and websites managed by wholesale distributors do not differentiate Par's Potassium Chloride Powder product from Defendants' KLOR-CON Powder product, causing further deception and confusion.

53. On information and belief, Defendants mislead customers by not identifying their product as "unapproved" to Group Purchasing Organizations ("GPOs") and integrated delivery

networks ("IDNs"), which facilitate the purchase of prescription drugs to pharmacies. Such organizations and networks—which include Amerinet, HealthTrust, MedAssets, Novation, and Premier—maintain agreements with manufacturers for purchasing on a national basis various pharmaceutical products used by hospitals and other health care facilities. Hospitals and hospital pharmacies typically participate in such group purchasing programs, and agree to purchase the manufacturers' products under the terms negotiated by the GPO or IDN from wholesalers who are also participants in the GPO or IDN. GPOs and IDNs facilitate the purchase of Defendants' KLOR-CON Powder product without knowledge that it is not FDA approved.

54. On information and belief, Defendants also mislead customers by providing obsolete and incomplete information about their product to third-party drug pricing information aggregators ("Price Lists"), who provide pricing information for drugs and pharmaceutical equivalents of those drugs. Price Lists can be integrated with other computerized information systems used by, *e.g.*, GPOs, hospitals, and insurance companies, to allow purchasers to compare drugs and drug prices. Such Price Lists include, for example, Medi-Span and First Databank. On information and belief, although Defendants provide drug and pricing information for the unapproved KLOR-CON Powder in Price Lists, Defendants intentionally provide obsolete and incomplete information about KLOR-CON Powder to the Price Lists in order to mislead customers.

55. For example, a customer who searches for potassium chloride oral packet 20 mEq will see Par's FDA approved product alongside Defendants' unapproved KLOR-CON Powder product, as depicted below:

Search Results for Product Name: **Potassium Chloride Oral Packet 20 MEQ** Include: ☐ Repackaged ☐ Inactives

Records 1 through 12 of 12 << < > >> Page 1

NDC/UPC/HRI	Product Name	Package Size	Package SUM	Package Qty	Package Desc	Labeler Name
00245-0035-89	Klor-Con Oral Packet 20 MEQ	1	EA	1	Packet	SANDOZ
66758-0120-34	Klor-Con Oral Packet 20 MEQ	30	EA	1	Box	SANDOZ
66758-0120-81	Klor-Con Oral Packet 20 MEQ	100	EA	1	Box	SANDOZ
00603-1554-04	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Box	PAR PHARMACEUTICALS
00603-1554-16	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Box	PAR PHARMACEUTICALS
51862-0135-01	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Box	MAYNE PHARMA
51862-0135-02	Potassium Chloride Oral Packet 20 MEQ	1	EA	1	Packet	MAYNE PHARMA
51862-0135-30	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Box	MAYNE PHARMA
64950-0321-01	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Packet	LEHIGH VALLEY TECHNOLOGIES
64950-0321-30	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Packet	LEHIGH VALLEY TECHNOLOGIES
76439-0343-10	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Box	VIRTUS PHARMACEUTICALS OPCO
76439-0343-30	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Box	VIRTUS PHARMACEUTICALS OPCO

(Exhibit 22.) The Price List search results do not differentiate Defendants' KLOR-CON Powder product as not FDA approved, and as a result, consumers are misled and falsely believe Defendants' product is interchangeable, equivalent, or the same as Par's FDA's approved Potassium Chloride Powder. Worse still, because Sandoz markets the product under the brand name KLOR-CON, customers falsely believe Par's product is a generic version of Defendants' brand-name product. Even the product information for Par's product identifies Defendants' unapproved product, as depicted below:

NDC/UPC/HRI	Product Name	Package Size	Package SUM	Package Qty	Package Description	Labeler Name	Labeler Code
00603-1554-16	Potassium Chloride Oral Packet 20 MEQ		30 EA		1 Box	PAR PHARMACEUTICALS	00603

GPI Cross Reference - Potassium Chloride Powder Packet 20 mEq (79-70-00-30-00-30-15) - Package Size 30

NDC/UPC/HRI	Product Name	AWP	DP	WAC	ACA FUL	AAWP	GEAP	AWAC	GEWAC	Labeler	MS	TEE	Rx
00245-0035-30	Klor-Con Oral Packet 20 MEQ	$203.74		$145.53		$190.15		$143.19		SANDOZ	Y	NR	R
00603-1554-16	Potassium Chloride Oral Packet 20 MEQ	$322.19		$227.70		$262.73		$200.34		PAR PHARMACEUTICALS	Y	NR	R
50268-0670-30	Potassium Chloride Oral Packet 20 MEQ	$222.59		$185.49				$301.68		AVPAK	Y	NR	R
51862-0135-30	Potassium Chloride Oral Packet 20 MEQ	$185.40		$139.05		$262.73		$200.34		MAYNE PHARMA	Y	NR	R
54868-0356-03	Potassium Chloride Oral Packet 20 MEQ	$107.49				$262.73		$200.34		PHYSICIANS TOTAL CARE	Y	NR	R
64950-0321-30	Potassium Chloride Oral Packet 20 MEQ	$362.02		$301.68				$301.68		LEHIGH VALLEY TECHNOLOGIES	Y	NR	R
66758-0120-34	Klor-Con Oral Packet 20 MEQ	$362.01		$289.60		$262.73		$200.34		SANDOZ	Y	NR	R
76439-0343-30	Potassium Chloride Oral Packet 20 MEQ	$181.32		$145.00		$262.73		$200.34		VIRTUS PHARMACEUTICALS OPCO	Y	NR	R

Ingredients (Set ID: 79763)

Ingredient Name	Strength	Units	Active	Generic ID
POTASSIUM CHLORIDE	20.0000	MEQ	Y	C007447407
FD&C YELLOW #6 (SUNSET YELLOW)	0.0000		N	C002783940

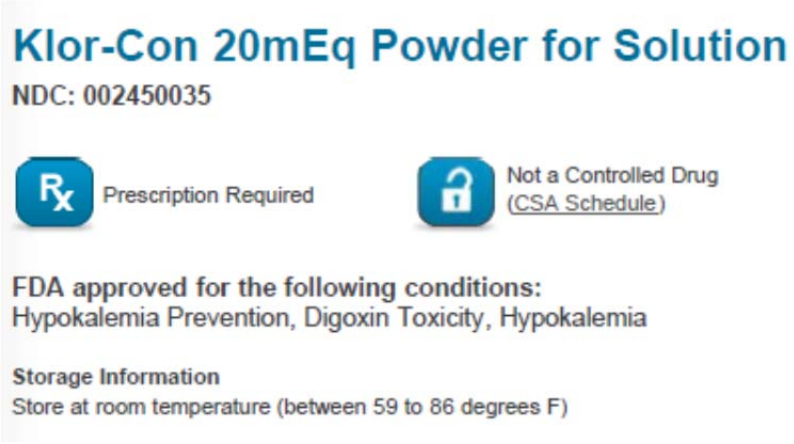
(Exhibit 17 at 5.)

56. On information and belief, Sandoz misleads retail pharmacists, hospital pharmacists, and hospital administrators (collectively, "pharmacists") who purchase Defendants' KLOR-CON Powder product from wholesale distributors, or through GPOs or IDNs, by hiding

the material fact that Defendants' product is not FDA approved. Because Defendants do not differentiate their unapproved product and Par's approved product, pharmacists are misled into falsely believing that Defendants' KLOR-CON Powder product is FDA approved. Furthermore, physicians writing prescriptions for potassium chloride powder do not know which drug product—*e.g.*, Par's approved product or Defendants' unapproved product—is sold to patients and hospitals when the prescription is filled by pharmacists.

Based on Defendants' Misleading Advertising,
Customers Are Actually Deceived and Confused

57. The misleading nature of Defendants' advertising of their KLOR-CON Powder is evidenced by CVS Pharmacy's website listing Defendants' KLOR-CON Powder product as FDA approved, as depicted below:



(Exhibit 5 at 2.) CVS Pharmacy mistakenly states the product is "FDA approved for the following conditions: Hypokalemia Prevention, Digoxin Toxicity, Hypokalemia."

58. The misleading nature of Defendants' advertising of their KLOR-CON Powder is further evidenced by the Physicians Desk Reference ("PDR"), which lists KLOR-CON Powder for Oral Solution as the only "brand" potassium chloride powder product. (*See* Exhibit 19 at 1.) Not only is KLOR-CON Powder not a branded pharmaceutical product approved by an NDA, it

is not approved whatsoever. According to the PDR: "The PDR Websites, the PDR Applications and the PDR Services display pharmaceutical drug products' FDA-approved or other manufacturer-supplied labeling. Under the Federal Food, Drug and Cosmetic ('FD&C') Act, a manufacturer may label, promote, and advertise a drug approved for marketing only for those uses for which the drug's safety and effectiveness have been established." (Exhibit 18 at 3.) Thus, a physician looking for information about Defendants' KLOR-CON Powder using the PDR would be misled to believe that the product is FDA approved.

59. The misleading nature of Defendants' advertising of their KLOR-CON Powder is further evidenced by the statement on the www.drugs.com website that KLOR-CON is approved by the FDA. (Exhibit 8 at 1.) Drugs.com also states that generic versions of KLOR-CON have been approved, which is misleading because KLOR-CON Powder itself is not FDA approved.

60. The misleading nature of Defendants' advertising of their KLOR-CON Powder is further evidenced by Kaiser Permanente's website, which identifies KLOR-CON 20 mEq oral packet as the brand drug, and "potassium solution/powder for solution - oral" as the "generic name." (Exhibit 21 at 1.) Identifying a drug as a brand indicates that the drug has been approved by the FDA.

61. The misleading nature of Defendants' advertising of their KLOR-CON Powder is further evidenced by Monthly Prescribing Reference, which lists KLOR-CON Rx as a branded drug, along with "generic name and formulations." (Exhibit 20 at 1.) KLOR-CON Powder is not an FDA approved branded drug, and other potassium chloride powder are not generic versions of KLOR-CON.

Plaintiffs Are Injured by Defendants' False Advertising

62. According to the above-mentioned recent IMS data, Defendants' KLOR-CON

Powder product accounts for approximately 33% of the U.S. market. In contrast, because of Defendants' conduct alleged herein, Par's sales only account for approximately 2% of the market. Because pharmacists prefer to purchase and dispense FDA approved prescription drugs over unapproved drugs, because Par's Potassium Chloride Powder product is the only FDA approved product in this market, and because Par has the capacity to supply pharmacies with the entire market demand for potassium chloride powder for oral solution, Par would likely fill most or all of Defendants' current market share but for Defendants' false advertising.

63. Defendants' conduct has further injured Plaintiffs because it has prevented Plaintiffs from achieving a fair market price. Because Defendants unfairly compete with Par's product, Plaintiffs are unable to achieve a fair market price for Par's product. Consumers choose Defendants' unapproved product because they are misled by Defendants that such products are FDA approved. But for Defendants' conduct, Plaintiffs would be able to achieve a higher market penetration at higher prices due to their position as the only FDA approved Potassium Chloride Powder product on the market. As a result of Plaintiffs' inability to achieve a higher marketed penetration at higher prices, Plaintiffs cannot recoup their expenditures related to obtaining FDA approval of their Potassium Chloride Powder product.

COUNT I:
FALSE ADVERTISING AND UNFAIR COMPETITION
UNDER 15 U.S.C. § 1125(a)
(AGAINST SANDOZ AND UPSHER-SMITH)

64. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–63 of this Complaint.

65. On information and belief, Defendants advertise, promote, distribute, and sell their KLOR-CON Powder product throughout the United States and New Jersey to wholesale distributors, GPOs, IDNs, hospitals, outpatient centers, pharmacists, physicians, and patients.

66. Defendants advertise, promote, distribute, and sell their KLOR-CON Powder product by making false and misleading statements, omissions, and other tactics likely to create false impressions and confusion regarding the FDA approval status of the KLOR-CON Powder product. Sandoz makes literally false statements such as the advertisement in the Pocket Guide that the KLOR-CON Powder product is a "brand" drug, which necessarily connotes it was approved by the FDA. (Exhibit 4 at 40, 73.) This statement is literally false because the Sandoz KLOR-CON Powder is an unapproved drug.

67. In addition, Sandoz makes literally false statements such as the advertisement in the Pocket Guide that the potassium chloride powder is a "generic" drug, which necessarily connotes it was approved by the FDA. (Exhibit 4 at 40, 73.) This statement is literally false because (i) Par's Potassium Chloride Powder is the only FDA approved potassium chloride powder product; and (ii) no company has an approved ANDA from the FDA. In multiple places on its website, Sandoz touts the fact that it is a "generic" drug company that specializes in the manufacture and sale of "generic" drugs. It emphasizes that "generic" drugs are approved by the FDA. These statements, considered in their entirety, are literally false because they convey the necessary implication that all prescription drugs Sandoz sells are approved by the FDA.

68. Defendants' product packaging, their websites, and their intentional omission of the fact that the product is unapproved from wholesale supplier websites, GPO, IDN, and Price List websites, each deceive a substantial segment of customers. Defendants' false advertising causes buyers to mistakenly conclude that Defendants' KLOR-CON Powder product is either interchangeable with Par's FDA approved product or, even worse, that Defendants' unapproved product is the brand and Par's FDA approved product is a generic version of it.

69. The FDA approval status of a drug product is material to customers, including

pharmacists and end users. Defendants misrepresent the nature, characteristics and qualities of the unapproved KLOR-CON Powder through the packaging, commercial advertising, and promotion of this product.

70. As a direct result of Defendants' false and misleading descriptions of fact, false and misleading representations, and false and deceptive advertising and unfair competition, there is actual deception or at least a tendency to deceive a substantial portion of the intended audience.

71. As a direct result of Defendants' false and misleading descriptions of fact, false and misleading representations, and false and deceptive advertising and unfair competition, Plaintiffs have suffered, currently suffer, and will continue to suffer damage and irreparable injury, including injury to their business, reputation, and goodwill.

72. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Lanham Act violations, an accounting for profits made by Sandoz on sales of KLOR-CON Powder product, as well as recovery of costs of this action. Furthermore, the conduct alleged herein was undertaken willfully and with the intention of causing confusion, mistake, or deception, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorney fees pursuant to 15 U.S.C. § 1117.

73. Defendants' conduct has caused, and will continue to cause, immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. As such, Plaintiffs are also entitled to injunctive relief as set forth in 15 U.S.C. § 1116.

74. Defendants' unlawful conduct including, *inter alia*, advertising, promotion, selling, and distribution of an unapproved KLOR-CON Powder product has harmed and will continue to irreparably harm Plaintiffs and pose grave risks to New Jersey purchasers, residents,

and other consumers.

COUNT II:
STATUTORY FALSE ADVERTISING
UNDER THE NEW JERSEY FAIR TRADE ACT
(AGAINST SANDOZ AND UPSHER-SMITH)

75. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–74 of this Complaint.

76. Defendants have engaged in unfair competition and false advertising practices arising under New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq*., through their conduct alleged herein, *inter alia*, making untrue and misleading statements in advertisements and promotions causing at least a likelihood of confusion or misunderstanding of the FDA approval of the unapproved Potassium Chloride Powder.

77. Defendants acted willfully during the time period relevant to this action, and Defendants unlawfully derived and will continue to derive income profits and goodwill from their wrongful activities. Defendants' conduct has caused, and will continue to cause, immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. As an actual and proximate result of Defendants' willful and intentional actions, Plaintiffs have and will continue to suffer damages, including lost sales, revenue, market share, and asset value in an amount to be determined at trial, and unless Defendants are restrained, Plaintiffs will continue to suffer irreparable harm.

COUNT III:
COMMON LAW UNFAIR COMPETITION
(AGAINST SANDOZ AND UPSHER-SMITH)

78. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–77 of this Complaint.

79. Par's Potassium Chloride Powder is the only FDA approved potassium chloride

powder product in the United States. Plaintiffs have a reasonable expectation of selling their product in the United States. Other companies, including Defendants, sell unapproved versions of the drug, and among other things, interfere with Plaintiffs' current and future sales of their product.

80. As a result of Defendants' actions described herein, Plaintiffs have suffered and will continue to suffer substantial damage to their business, reputation, and goodwill; and Defendants' actions constitute a significant threat to Plaintiffs' ability to compete in the marketplace.

81. Defendants' conduct has caused, and will continue to cause, immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. As a direct and proximate result of Defendants' willful and intentional actions, Plaintiffs have and will continue to suffer damages, including lost sales, revenue, market share, and asset value in an amount to be determined at trial. Plaintiffs suffer irreparable damage, and unless Defendants are restrained, Plaintiffs will continue to suffer irreparable damage.

COUNT IV:
CONTRIBUTORY FALSE ADVERTISING
15 U.S.C. § 1125(a)
(AGAINST UPSHER-SMITH)

82. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–81 of this Complaint.

83. On information and belief, based on the conduct alleged herein, Sandoz has engaged in false advertising that has injured Plaintiffs.

84. On information and belief, Upsher-Smith actively engages in the false advertising, but Upsher-Smith is alternatively contributorily liable because it induces Sandoz's misleading conduct. Upsher-Smith contributes to Sandoz's false advertising because, for example, Upsher-

Smith supplies, manufactures, labels, and packages the unapproved KLOR-CON Powder product, knows or should know about Sandoz's conduct alleged herein, and directly or indirectly, ships it, to or on behalf of Sandoz, into New Jersey.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court enter judgment against Sandoz and Upsher-Smith as follows:

A. That Defendants and all of their respective officers, agents, representatives, employees, attorneys, and all other persons acting in concert with them be permanently enjoined from:

1. listing the unapproved KLOR-CON Powder product on the prescription drug dispensing databases, including but not limited to Medi-Span and First Databank, until such time as those databases provide clear and conspicuous notice that Defendants' KLOR-CON Powder is not FDA approved;

2. directly or indirectly engaging in false advertising or promotions of the unapproved KLOR-CON Powder product or using such advertising or promotions to induce others to substitute the unapproved KLOR-CON Powder product for Par's FDA approved Potassium Chloride Powder product;

3. making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution (including but not limited to repackaging) of the unapproved KLOR-CON Powder product in such a fashion as to suggest that such product is a generic version of or equivalent to Par's FDA approved Potassium

Chloride Powder product, or can be interchanged with or substituted for prescriptions of Par's FDA approved Potassium Chloride Powder product; and

4. directly or indirectly engaging in false advertising or promotions of the unapproved KLOR-CON Powder product as FDA approved, including any representation, description, or statement that would imply that their product is interchangeable or an equivalent of any previously approved Potassium Chloride Powder product; which representation, description or statement may mislead others to believe that Defendants' product is FDA approved;

B. That Sandoz and Upsher-Smith be ordered to correct any erroneous impression consumers may have derived concerning the nature, characteristics, or qualities of either the unapproved KLOR-CON Powder product or Par's FDA approved Potassium Chloride Powder product, including without limitation:

1. sending a registered letter (with a copy to Plaintiffs) to all databases that list the unapproved KLOR-CON Powder product, including but not limited to Medi-Span and First Databank, requesting that the unapproved KLOR-CON Powder product be immediately listed as obsolete in said Price List databases, and instructing them to remove any listing of KLOR-CON Powder product in said Price List databases or to insert a clear and conspicuous notice that the unapproved Potassium Chloride Powder product is not FDA approved as safe and effective for treating any condition, as soon as commercially possible;

2. placing corrective advertising, for a period of 12 months, in the form of a printed advertisement on their websites stating that the unapproved KLOR-CON Powder product is not FDA approved in a font no smaller than the font used throughout their websites; and

3. providing notice to each person or entity that purchased, dispensed, ordered and prescribed the unapproved KLOR-CON Powder product (including wholesale generic drug purchasers, pharmacists, GPOs, outpatient centers, hospitals, doctors, and purchasers or buyers of such products) that the FDA has approved only Par's Potassium Chloride Powder product;

4. providing a disclaimer on Defendants' packaging stating that the product is not FDA approved;

C. That Sandoz and Upsher-Smith be adjudged to have violated the provisions of 15 U.S.C. § 1125(a) by unfairly competing against Plaintiffs by using false or, misleading descriptions or representations of fact that misrepresent the nature, quality, and characteristics of KLOR-CON Powder product;

D. That Sandoz and Upsher-Smith be adjudged to have unlawfully competed against Plaintiffs by engaging in unfair competition and false advertising under New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq*.

E. That Sandoz and Upsher-Smith be adjudged to have unlawfully competed against Plaintiffs by engaging in unfair competition under the common law;

F. That Sandoz and Upsher-Smith recall and remove their unapproved KLOR-CON Powder product from the distribution supply chains until such time as they clearly and conspicuously state that the unapproved KLOR-CON Powder product is not FDA approved;

G. That Plaintiffs be awarded damages pursuant to 15 U.S.C. § 1117, sufficient to compensate it for the damage caused by the false and misleading statements related to KLOR-CON Powder;

H. That Plaintiffs be awarded profits derived by reason of said acts, or as determined by an accounting;

I. That such damages and profits be trebled and awarded to Plaintiffs and that they be awarded their costs, attorneys' fees and expenses in this suit under 15 U.S.C. § 1117, as a result of the willful, intentional and deliberate acts alleged herein in violation of the Lanham Act;

J. That Plaintiffs be awarded damages in an amount sufficient to compensate them for the damage caused by Sandoz's and Upsher-Smith's unlawful competition and false or misleading acts and deceptive trade practices under the New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq.* and the common law;

K. That Plaintiffs be granted injunctive relief under the New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq.*;

L. That all of Sandoz's and Upsher-Smith's misleading materials and products be destroyed as allowed under 15 U.S.C. § 1118;

M. That Sandoz and Upsher-Smith file, within ten days from entry of an injunction, a declaration with this Court signed under penalty of perjury certifying the manner in which Sandoz and Upsher-Smith have complied with the terms of the injunction;

N. That Plaintiffs be granted pre-judgment and post-judgment interest;

O. That Plaintiffs be granted costs associated with the prosecution of this action; and

P. That Plaintiffs be granted such further relief as the Court may deem just.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury of all issues in this case.

Respectfully submitted,

K&L GATES LLP

Dated: June 22, 2016 By: s/ Loly G. Tor

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in the above-captioned action, to the best of my knowledge, is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: June 22, 2016

By: s/ Loly G. Tor

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